

120.020: REGISTRATION OF RADIATION MACHINE FACILITIES AND SERVICES

120.021: Purpose and Scope

(A) 105 CMR 120.020 through 120.040 provides for the registration of radiation machine facilities and for the registration of persons providing radiation machine installation, servicing, and/or services to Department registrants or registrable facilities. For the purposes of 105 CMR 120.020, particle accelerators, whether used primarily for x-ray production or other purposes, shall be considered a radiation machine facility.

(B) In addition to the requirements of 105 CMR 120.020 through 120.040, all registrants are subject to the applicable provisions of other parts of 105 CMR 120.000.

120.022: Definitions

As used in 105 CMR 120.020 through 120.040, "facility" means the location at which one or more devices or sources are installed and/or located within one building, vehicle, or under one roof and are under the same administrative control.

120.023: Exemptions

(A) Electronic equipment that produces radiation incidental to its operation for other purposes is exempt from the registration and notification requirements of 105 CMR 120.020 through 120.040, providing dose equivalent rate averaged over an area of ten square centimeters does not exceed 0.5 millirem ($5\mu\text{Sv}$) per hour at five centimeters from any accessible surface of such equipment. The production, testing, or factory servicing of such equipment shall not be exempt.

(B) Radiation machines while in transit or storage incident thereto are exempt from the requirements of 105 CMR 120.020 through 120.040.

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(C) Domestic television receivers are exempt from the requirements of 105 CMR 120.020 through 120.040.

120.024: Plan Review

(A) Prior to construction, the floor plans and equipment arrangements of all new installations, or modifications of existing installations, utilizing ionizing radiation for diagnostics or therapeutic purposes shall be submitted to the Agency for review and approval. The installation shall meet the requirements of 105 CMR 120.420: *Appendix A* and 105 CMR 120.422: *Appendix C* unless specifically exempted. Additional shielding and design requirements are specified elsewhere in 105 CMR 120.000.

(B) The Agency may require the applicant to utilize the services of a qualified expert to determine the shielding requirements prior to the plan review and approval.

(C) The approval of such plans shall not preclude the requirement of additional modifications should a subsequent analysis of operating conditions indicate the possibility of an individual receiving a dose in excess of the limits prescribed in 105 CMR 120.211, 120.217, 120.218 and 120.221.

120.025: Application for Registration

Each person who owns or possess and administratively controls a facility, unless specifically exempted in 105 CMR 120.023 shall:

(A) Apply for registration of such facility with the Agency prior to the operation of a radiation machine facility. Application for registration shall be completed on forms furnished by the Agency and shall contain all the information required by the form and accompanying instructions.

(B) Designate on the application form an individual to be responsible for radiation protection.

(C) Each registrant shall prohibit any person from furnishing radiation machine servicing or services as described in 105 CMR 120.026(D) to his radiation machine facility until such person provides evidence that he has been registered with the Agency as a provider of services in accordance with 105 CMR 120.026.

120.026: Application for Registration Services

(A) Each person, prior to engaging in the business of installing or offering to install radiation machines or engaging in the business of furnishing or offering to furnish radiation machine servicing or services in this Commonwealth shall apply for and receive registration for such services with the Agency.

(B) Application for registration shall be completed on forms furnished by the Agency and shall contain all information required by the Agency as indicated on the forms and accompanying instructions.

(C) Each person applying for registration under 105 CMR 120.020 through 120.040 shall specify:

- (1) That he has read and understands the requirements of 105 CMR 120.020 through 120.040;
- (2) The services for which he is applying for registration; and,
- (3) The training and experience that qualify him to discharge the services for which he is applying for registration;

(D) For the purpose of 105 CMR 120.026, services may include but shall not be limited to:
(1) Installation and/or servicing of radiation machines and associated radiation machine components;

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- (2) Calibration of radiation machines or radiation measurement instruments or devices;
- (3) Radiation protection or health physics consultations or surveys; and,
- (4) Personnel dosimetry services.

120.027: Certificate of Registration

- (A) No person shall maintain a facility that is required by 105 CMR 120.000 to be registered unless such a person has obtained a valid certificate of registration for such facility.
- (B) A person who applies for registration and whose application meets the requirements of 105 CMR 120.000, shall, upon payment of the required fee, be issued a certificate of registration effective on the date stated on such certificate.
- (C) A current certificate of registration or a legible copy thereof shall be posted conspicuously at each registered facility.
- (D) The Director of the Radiation Control Program may incorporate in the certificate of registration, at the time of issuance or thereafter, any such additional requirements and conditions with respect to the registrant's receipt, possession, use, and transfer of radiation machines as said Director finds appropriate and necessary for the protection of the general public or individuals against radiation hazards.

120.028: Expiration of Notice of Registration

Each certificate of registration shall expire at the end of the specified day in the month and year stated therein.

120.029: Renewal of Notice of Registration

- (A) Application for renewal of registration shall be filed in accordance with 105 CMR 120.025 or 105 CMR 120.026.
- (B) In any case in which a registrant not less than 30 days prior to the expiration of his existing notice of registration has filed an application in proper form for renewal, such existing notice of registration shall not expire until the application status has been finally determined by the Agency.

120.030: Report of Changes

The registrant shall notify the Agency in writing before making any change which would render the information contained in the application for registration and/or the certificate of registration no longer accurate. In the case of disposition of an x-ray system, such notification should specify the recipient of the system. In the case of modification involving a structural change, or the addition or relocation of an x-ray system, the Director of the Radiation Control Program may require the registrant to submit the information contained in 105 CMR 120.420: *Appendix A* and/or 105 CMR 120.421: *Appendix C*.

120.031: Approval Not Implied

No person, in any advertisement, shall refer to the fact that he or his facility is registered with the Agency pursuant to the provisions of 105 CMR 120.025 or 120.026, and no person shall state or imply that any activity under such registration has been approved by the Agency.

120.032: Assembler and/or Transfer Obligation

- (A) Any person who sells, leases, transfers, lends, disposes, assembles, or installs radiation machines in this Commonwealth shall notify the Agency within 15 days of:
 - (1) The name and address of persons who have received these machines;
 - (2) The manufacturer, model, and serial number of each radiation machine transferred; and,
 - (3) The date of transfer of each radiation machine.

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(4) In the case of diagnostic x-ray system which contain certified components, a copy of the assembler's report prepared in compliance with requirements of the Federal Diagnostic X-Ray Standard (21 CFR 1020.30 (d)) shall be submitted to the Agency within 15 days following completion of the assembly. Such report shall suffice in lieu of any other by the assembler.

(B) No person shall make, sell, lease, transfer, lend, assemble, or install radiation machines or the supplies used in connection with such machines unless such supplies and equipment when properly placed in operation and use shall meet the requirements of 105 CMR 120.000.

120.033: Out-of-state Radiation Machines

(A) Whenever any radiation machine is to be brought into the Commonwealth, for any temporary use, the person proposing to bring such machine into the Commonwealth shall give written notice to the Agency at least ten working days before such machine is to be used in the Commonwealth. The notice shall include:

- (1) The type of radiation machine;
- (2) The nature, duration, and scope of use;
- (3) The exact location(s) where the radiation machine is to be used; and,
- (4) States in which this machine is registered.

(B) The person referred to in 105 CMR 120.033 shall:

- (1) Comply with all applicable regulations of the Agency;
- (2) Register the radiation machine(s) with the Agency; and,
- (3) Submit payment of the required fee for registration.

(C) A pre-operational inspection may be required at the discretion of the Director of the Radiation Control Program.

(D) If, for a specific case, the ten working day period is not practical, notification to the Agency by telephone and hardcopy, permission to proceed sooner may be granted.

120.040: Notification to Fire Department

The user shall notify the local fire department of the presence on his premises of any radioactive material that may present special fire-fighting problems or require special precautionary measures in case of fire or other natural catastrophe, and he shall establish effective liaison with the fire department in regards to this matter.